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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,088	01/26/2006	Michael J. Caulfield	21468YP	5491

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

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03/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,088	CAULFIELD ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Prodhomme et al. 2000*.

Lack of Unity & Species Election

1) Claims 1-13 are under prosecution.

2) This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-9, drawn to a conjugate comprising poly-D-gamma glutamic acid of over 100 kDa covalently linked to an immunogenic carrier protein and a vaccine comprising the same.

II. Claim 10, drawn to a method of vaccinating a patient comprising administering a conjugate comprising poly-D-gamma glutamic acid of over 100 kDa covalently linked to an immunogenic carrier protein.

III. Claims 11 and 12, drawn to a method of making a conjugate of poly-D-gamma glutamic acid and a carrier protein under non-aqueous conditions.

IV. Claim 13, drawn to a method of purifying poly-D-gamma glutamic acid using hydroxyapatite chromatography column.

3) Inventions I-IV lack unity. The special technical feature of the first invention is a conjugate comprising poly-D-gamma glutamic acid of over 100 kDa covalently linked to an immunogenic carrier protein. However, such a product was already disclosed in the art at the time of the invention. For example, Prodhomme *et al.* (*In*: *Abstracts of the 219th ACS National Meeting*. March 26-30, 2000, San Francisco, CA. # 133, American Chemical Society, Washington, D.C.) taught a conjugate of poly-D-gamma glutamic acid of over 100 kDa conjugated to an antibody protein. See abstract. Thus, the product of claim 1 does not define over the prior art. Although the product of invention I, and the method of using the product of invention II and the method of making the product of invention III, is a permitted combination under PCT Rule 13.2, in the instant case, since the product is already disclosed in the art, the special technical feature is not a unifying feature. Technically, the absence of special technical feature permits the separation of the method of using or making the product from the product

itself. The method of invention IV lacks significant common method steps and reagents used with the methods of inventions II and III.

4) The Office has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

5) In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See '*Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)', 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. 37 CFR 1.143.

7) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

8) This application contains claims directed to more than one carrier protein species, and additional antigen species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

(A) Carrier protein species:

(a) OMPC of *Neisseria meningitidis* (claims 5, 6 and 8);

(b) Tetanus toxoid (claim 5);

(c) Diphtheria toxoid (claim 5);

(d) HBsAg (claim 5);

(e) HBcAg (claim 5);

(f) Recombinant protective antigen of HPVVLP type 6 (claim 5);

(g) Recombinant protective antigen of HPVVLP type 11 (claim 5);

(h) Recombinant protective antigen of HPVVLP type 16 (claim 5);

(i) L1 protein of HPVVLP type 6 (claim 5);

(j) L1 protein of HPVVLP type 11 (claim 5); and

(k) L1 protein of HPVVLP type 16 (claim 5).

Claims 1-4, 7 and 9 are generic.

(B) Additional antigen species (claim 9):

(i) *Haemophilus influenzae* antigen;

(ii) Hepatitis virus A;

(iii) Hepatitis virus B;

(iv) Hepatitis virus C;

(v) M2 epitopes of Influenza virus type A;

(vi) M2 epitopes of Influenza virus type B;

(vii) Haemagglutinin of Influenza virus type A;

(viii) Haemagglutinin of Influenza virus type B;

(ix) Neuraminidase of Influenza virus type A;

(x) Neuraminidase of Influenza virus type B;

(xi) Human papilloma virus antigen;

(xii) Measles antigen;

(xiii) Mumps antigen;

(xiv) Rubella antigen;

(xv) Varicella antigen;

(xvi) Rotavirus antigen;

(xvii) *Streptococcus pneumoniae* antigen; and

(xviii) *Staphylococcus aureus* antigen.

Claims 1-8 are generic.

9) The species identified above do not share significant common structure, biochemical, antigenic, and/or immunonospecific characteristics. These species have mutually exclusive structural, antigenic and/or immunospecific features.

10) Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A telephone message may be left on the Examiner's voice mail system. The Examiner can

normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (703) 308-0898.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/S. Devi, Ph.D/
Primary Examiner
AU 1645

March, 2008